HFA-200

Approval Date: JAN 12 2007

FREEDOM OF INFORMATION SUMMARY

ORIGINAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-415

Gentamicin Sulfate Topical Spray
(gentamicin sulfate, USP with betamethasone valerate, USP)

Indicated for the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin

Sponsored by:

First Priority, Inc.

2007.200.415

FOIS 1

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a. File Number:	ANADA 200-415
b. Sponsor:	First Priority, Inc. 1585 Todd Farm Drive Elgin, IL 60123 Drug Labeler Code: 058829
c. Established Name:	Gentamicin sulfate, betamethasone valerate
d. Proprietary Name:	Gentamicin Sulfate Topical Spray
e. Dosage Form:	Liquid
f. How Supplied:	60 mL, 120 mL, and 240 mL spray bottles
g. How Dispensed:	Rx
h. Amount of Active Ingredients:	Each mL contains: gentamicin sulfate, USP equivalent to 0.57 mg gentamicin base, betamethasone valerate, USP equivalent to 0.284 mg betamethasone.
i. Route of Administration:	Topical
j. Species/Class:	Dogs
k. Recommended Dosage:	Two depressions of the sprayer head 2 to 4 times daily for 7 days. Each depression of the sprayer head delivers 0.7 mL of Gentamicin Sulfate Topical Spray.
l. Pharmacological Category:	Antimicrobial
m. Indications:	For the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin.
n. Pioneer Product:	GENTOCIN Topical Spray (gentamicin sulfate, betamethasone valerate) NADA 132-338; Schering-Plough Animal Health Corporation

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) of 1988, an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, First Priority, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product Gentamicin Sulfate Topical Spray (gentamicin sulfate, betamethasone valerate). The generic product is administered as a topical, contains the same active ingredients in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredient. The pioneer product, GENTOCIN Topical Spray (gentamicin sulfate, betamethasone valerate) the subject of Schering-Plough Animal Health Corp, NADA 132-338, was approved on January 7, 1985.

3. HUMAN SAFETY:

This drug is intended for use in dogs, which are non-food animals. Because this drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this ANADA.

4. AGENCY CONCLUSIONS:

This ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that GENTOCIN Topical Spray, when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

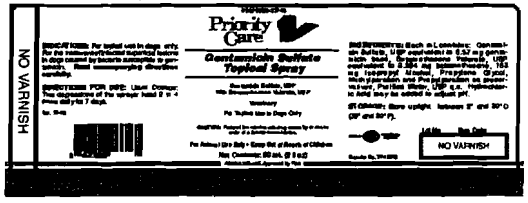
Facsimile generic labeling and currently approved pioneer labeling are attached as follows:

Generic Labeling for ANADA 200-415:
Product label, 60 mL package size
Product label, 120 mL package size
Product label, 240 mL package size
Package Insert

Pioneer Labeling for NADA 132-338:
Product label, 72 mL package size
Package insert
Product case, 72 mL package size

60 mL Bottle

Actual Label Size
1.875 x 5



Enlargement

NO VARNISH

NDC# 58829-337-60

Priority Care

Gentamicin Sulfate Topical Spray

Gentamicin Sulfate, USP
With Betamethasone Valerate, USP

Veterinary

For Topical Use in Dogs Only

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

For Animal Use Only • Keep Out of Reach of Children

Net Contents: 60 mL (2 fl oz)

ANADA 200-415, Approved by FDA

INDICATIONS: For topical use in dogs only. For the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin. **Read accompanying directions carefully.**

DIRECTIONS FOR USE: Usual Dosage: Two depressions of the sprayer head 2 to 4 times daily for 7 days.

Iss. 10-06

3 62308

INGREDIENTS: Each mL contains: Gentamicin Sulfate, USP equivalent to 0.57 mg gentamicin base, Betamethasone Valerate, USP equivalent to 0.284 mg betamethasone, 163 mg Isopropyl Alcohol, Propylene Glycol, Methylparaben and Propylparaben as preservatives, Purified Water, USP q.s. Hydrochloric Acid may be added to adjust pH.

STORAGE: Store upright between 2° and 30°C (36° and 86°F).

TAKE TIME DIRECTIONS

Lot No. Exp. Date

NO VARNISH

Reorder No. TP410PC

120 mL Bottle

Actual Label Size
3 x 4.75

NDC# 58829-337-12

Priority Care

INDICATIONS: For topical use in dogs only. For the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin. Read accompanying directions carefully.

DIRECTIONS FOR USE: Usual Dosage: Two depressions of the sprayer head 2 to 4 times daily for 7 days.

Iss. 10-06

3 62308

Gentamicin Sulfate Topical Spray

Gentamicin Sulfate, USP
With Betamethasone Valerate, USP
Veterinary
For Topical Use in Dogs Only

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

For Animal Use Only • Keep Out of Reach of Children

Net Contents: 120 mL (4 fl oz)

ANADA 200-415, Approved by FDA

INGREDIENTS: Each mL contains: Gentamicin Sulfate, USP equivalent to 0.57 mg gentamicin base, Betamethasone Valerate, USP equivalent to 0.284 mg betamethasone, 163 mg Isopropyl Alcohol, Propylene Glycol, Methylparaben and Propylparaben as preservatives, Purified Water, USP q.s. Hydrochloric Acid may be added to adjust pH.

STORAGE: Store upright between 2° and 30°C (36° and 86°F).

Lot No. Exp. Date

NO VARNISH

Reorder No. TP411PC

240 mL Bottle

Actual Label Size
4.375 x 5.875

NDC# 58829-337-24

Priority Care

Gentamicin Sulfate Topical Spray

Gentamicin Sulfate, USP
With Betamethasone Valerate, USP
Veterinary
For Topical Use in Dogs Only

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

For Animal Use Only • Keep Out of Reach of Children

Net Contents: 240 mL (8 fl oz)

ANADA 200-415, Approved by FDA

INDICATIONS: For topical use in dogs only. For the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin. **Read accompanying directions carefully.**

DIRECTIONS FOR USE: Usual Dosage: Two depressions of the sprayer head 2 to 4 times daily for 7 days.

TAKE THE DIRECTIONS

Iss. 10-06

3 62308

INGREDIENTS: Each mL contains: Gentamicin Sulfate, USP equivalent to 0.57 mg gentamicin base, Betamethasone Valerate, USP equivalent to 0.284 mg betamethasone, 163 mg Isopropyl Alcohol, Propylene Glycol, Methylparaben and Propylparaben as preservatives, Purified Water, USP q.s. Hydrochloric Acid may be added to adjust pH.

STORAGE: Store upright between 2° and 30°C (36° and 86°F).

Lot No. Exp. Date

NO VARNISH

Reorder No. TP412PC

Gentamicin Sulfate Topical Spray

Gentamicin Sulfate, USP with
Betamethasone Valerate

Veterinary
For Topical Use in Dogs Only

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: Each mL contains: gentamicin sulfate, USP equivalent to 0.57 mg gentamicin base, betamethasone valerate, USP equivalent to 0.284 mg betamethasone, 163 mg isopropyl alcohol, propylene glycol, methylparaben and propylparaben as preservatives, purified water q.s. Hydrochloric acid may be added to adjust pH.

CHEMISTRY: Gentamicin is a mixture of aminoglycoside antibiotics derived from the fermentation of *Micromonospora purpurea*. Gentamicin sulfate veterinary is a mixture of sulfate salts of the antibiotics produced in this fermentation. The salts are weakly acidic and freely soluble in water.
Gentamicin sulfate veterinary contains not less than 500 micrograms of gentamicin base per milligram.
Betamethasone valerate is a synthetic glucocorticoid.

PHARMACOLOGY: Gentamicin, a broad-spectrum antibiotic, is a highly effective topical treatment for bacterial infections of the skin. *In vitro*, gentamicin is bactericidal against a wide variety of gram-positive and gram-negative bacteria isolated from domestic animals.[1,2] Specifically, gentamicin is active against the following organisms isolated from canine skin: *Alcaligenes* sp., *Citrobacter* sp., *Klebsiella* sp., *Pseudomonas aeruginosa*, indole-positive and -negative *Proteus* sp., *Escherichia coli*, *Enterobacter* sp., *Staphylococcus* sp., and *Streptococcus* sp.
Betamethasone valerate emerged from intensive research as the most promising of some 50 newly synthesized corticosteroids in the experimental model described by McKenzie,[3] et al. This human bioassay technique has been found reliable for evaluating the vasoconstrictor properties of new topical corticosteroids and is useful in predicting clinical efficacy.
Betamethasone valerate in veterinary medicine has been shown to provide anti-inflammatory and antipruritic activity in the topical management of corticosteroid-responsive infected superficial lesions in dogs.

WARNING: Clinical and experimental data have demonstrated that corticosteroids administered orally or parenterally to animals may induce the first stage of parturition when administered during the last trimester of preganancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.
Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have produced cleft palate. Other congential anomalies including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs that received corticosteroids during pregnancy.

INDICATIONS: For the treatment of infected superficial lesions in dogs caused by bacteria susceptible to gentamicin.

CONTRAINDICATIONS: If hypersensitivity to any of the components occurs, discontinue treatment and institute appropriate therapy.

DOSAGE AND ADMINISTRATION: Prior to treatment, remove excessive hair and clean the lesion and adjacent area. Hold bottle upright 3 to 6 inches from the lesion and depress the sprayer head twice. Administer 2 to 4 times daily for 7 days.
Each depression of the sprayer head delivers 0.7 mL of Gentamicin Sulfate Topical Spray.

TOXICITY: Gentamicin Sulfate Topical Spray was well-tolerated in an abraded skin study in dogs. No treatment-related toxicological changes in the skin were observed.
Systemic effects directly related to treatment were confined to histological changes in the adrenals, liver, and kidney and to organ-to-body weight ratios of adrenals. All were dose related, were typical for or not unexpected with corticosteroid therapy, and were considered reversible with cessation of treatment.

SIDE EFFECTS: Side effects such as SAP and SGPT enzyme elevations, weight loss, anorexia, polydipsia, and polyuria have occurred following parenteral or systemic use of synthetic corticosteroids in dogs. Vomiting and diarrhea (occasionally bloody) have been observed in dogs.
Cushing's syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

PRECAUTIONS: Antibiotic susceptibility of the pathogenic organism(s) should be determined prior to use of this preparation. Use of topical antibiotics may permit overgrowth of nonsusceptible bacteria, fungi, or yeasts. If this occurs, treatment should be instituted with other appropriate agents as indicated.
Administration of recommended dose beyond 7 days may result in delayed wound healing. Animals treated longer than 7 days should be monitored closely.
Avoid ingestion. Oral or parenteral use of corticosteroids, depending on dose, duration, and specific steroid may result in inhibition of endogenous steroid production following drug withdrawal.
In patients presently receiving or recently withdrawn from systemic corticosteroid treatments, therapy with a rapidly acting corticosteroid should be considered in especially stressful situations.
If ingestion should occur, patients should be closely observed for the usual signs of adrenocorticoid overdosage that include sodium retention, potassium loss, fluid retension, weight gains, polydipsia, and/or polyuria. Prolonged use or overdosage may produce adverse immunosuppressive effects.

HOW SUPPLIED: Plastic spray bottles containing 60 mL, 120 mL and 240 mL of Gentamicin Sulfate Topical Spray

Store upright between 2° and 30°C (36° and 86°F).

REFERENCES:

1. Hennessy PW, et al. *In vitro* activity of gentamicin against bacteria isolated from domestic animals. *Veterinary Medicine/Small Animal Clinician*. November 1971; 1118-1122.
2. Bachmann HJ, et al. Comparative *in vitro* activity of gentamicin and other antibiotics against bacteria isolated from clinical samples from dogs, cats, horses, and cattle. *Veterinary Medicine/Small Animal Clinician*. October 1975; 1218-1222.
3. McKenzie HW, Atkinson RM. Topical activities of betamethasone esters in man. *Arch Derm*. May 1964; 741-746.

Iss. 10-06

TAKE TIME  OBSERVE LABEL DIRECTIONS

Priority Care
...would you settle for less?

Manufactured by:
First Priority, Inc.
Elgin, IL 60123-1146

ANADA# 200-415,
Approved by FDA

Each mL contains: gentamicin sulfate, USP equivalent to 0.57 mg gentamicin base, betamethasone valerate, USP equivalent to 0.284 mg betamethasone, 163 mg isopropyl alcohol, propylene glycol, methylparaben and propylparaben as preservatives, purified water q.s. Hydrochloric acid may be added to adjust pH.

Usual Dosage: Two depressions of the sprayer head 2 to 4 times daily for 7 days.

Store upright between 2° and 30°C (36° and 86°F).

Read accompanying directions carefully.

 24280705 6/00

Gentocin®

(GENTAMICIN SULFATE, USP WITH BETAMETHASONE VALERATE)

Topical Spray

Veterinary

For topical use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

NADA #132-338, Approved by FDA.

Schering-Plough Animal Health

NDC 0061-0644-03

72 mL

PRODUCT INFORMATION

NADA #132-338, Approved by FDA.

Gentocin® TOPICAL SPRAY

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Veterinary
For Topical Use in Dogs Only

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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If ingestion should occur, patents should be closely observed for the usual signs of adrenocorticoid overdosage that include sodium retention, potassium loss, fluid retention, weight gains, polydipsia, and/or polyuria. Prolonged use or overdosage may produce adverse immunosuppressive effects.

HOW SUPPLIED: Plastic spray bottle containing 72 mL of GENTOCIN Topical Spray

Store upright between 2° and 30°C (36° and 86°F).

REFERENCES:

1. Hennessy PW, et al. *In vitro* activity of gentamicin against bacteria isolated from domestic animals. *Veterinary Medicine/Small Animal Clinician*. November 1971; 1118-1122.
2. Bachmann HJ, et al. Comparative *in vitro* activity of gentamicin and other antibiotics against bacteria isolated from clinical samples from dogs, cats, horses, and cattle. *Veterinary Medicine/Small Animal Clinician*. October 1975; 1218-1222.
3. McKenzie HW, Atkinson RM. Topical activities of betamethasone esters in man. *Arch Derm*. May 1964; 741-746.

June 2000
Schering-Plough Animal Health Corp.
Union, NJ 07083

Made in Ireland.

B-24281604

12 Bottles
72 mL Each

NDC 0061-0644-03

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Topical Spray
(GENTAMICIN SULFATE, USP WITH BETAMETHASONE VALERATE)

Veterinary

For topical use in dogs only.

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Topical Spray
(GENTAMICIN SULFATE, USP WITH BETAMETHASONE VALERATE)

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